INTERNATIONAL
Food
Additives
Council

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

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RE: Docket No. 96N-0417
Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

The International Food Additives Council (IFAC) is a trade association of producers of high purity substances used as food additives throughout the world. Many of these substances are Generally Recognized as Safe (GRAS) in the U.S. IFAC submits the following comments on the Food and Drug Administration's (FDA) proposed rule concerning "Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements."

IFAC is concerned specifically about FDA's explanation of proposed 21 CFR 111.35(d) which would require that all non-dietary ingredient components of dietary supplements be (1) Authorized for use as a food additive, (2) authorized by a prior sanction, (3) if used as a color additive, used in accordance with a listing that includes use in dietary supplements, or (4) GRAS. FDA asserts in the preamble that any claim that a substance is GRAS "must be supported by a citation to the agency's regulations or by an explanation for why there is general recognition of safety of the use of the substance in a dietary ingredient or a dietary supplement" and that "You could not use our response to your GRAS notification as your basis for asserting compliance with the requirements under §111.35(d) because an FDA response letter to a GRAS notification is not the same as your explanation, e.g., a response letter does not provide an explanation for why an ingredient is GRAS." IFAC is concerned that this would place an unreasonable burden on dietary supplement manufacturers who use GRAS ingredients. Dietary supplement manufacturers should be able to rely upon their supplier's assurance that a substance is GRAS and this, in turn, should satisfy the proposed GMP requirements.

IFAC is also concerned that since dietary supplements are foods FDA might expand this overly restrictive treatment of GRAS substances to conventional foods. For many GRAS substances having a long history of use, there may be a letter from FDA stating that the

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ingredient is GRAS for use in foods, but with no specific mention of its use as a dietary ingredient or in dietary supplements. Under these circumstances, use in dietary supplements should be permitted.

Otherwise, a number of substances with a long history of use in foods and possibly drugs and currently used in dietary supplements would be left in limbo relative to dietary supplements. What sort of documentation would the FDA require in such cases? For example, would a post 1958 FDA letter and a reference to the Inactive Ingredient Guide as published by FDA's Center for Drug Evaluation and Research (CDER) suffice?

There are also formulated products sold to the dietary supplement industry. In such cases, suppliers of such products might be required to provide confidential information (i.e., formula) to the dietary supplement producer in order for the producer to establish the safety of the product in accordance with FDA's proposed requirements. There is no mechanism in the proposal to protect confidential information such as that provided by the Drug Master File (Type IV). If it is FDA's intent that dietary ingredients and dietary supplements are to be regulated more like drugs than foods, there should be a mechanism to protect confidential information.

If a dietary supplement producer cannot rely on its supplier's determination that a substance is GRAS, even if that determination was the subject of a GRAS notification to which the agency did not object or about which the agency has stated it has no questions, each producer would have to make its own determination and have it available for every GRAS ingredient in a supplement. This would undermine the utility of a GRAS notification for purposes of customer assurance and as a means to conserve FDA resources.

IFAC objects to the FDA weakening the usefulness of the GRAS notification process. It should be permissible for a manufacturer to rely on the reasonable GRAS determination of its supplier. Furthermore, if a substance is acceptable for foods it should be acceptable for dietary ingredients and dietary supplements especially since foods are likely a greater source and consumed by more people than dietary supplements. IFAC requests that the agency reconsider its proposal as it relates to GRAS substances in dietary ingredients and supplements and rectify the difficulties it would create, for industry and for FDA.

Respectfully submitted,

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President

LON/jcr